

Dr. Nina Langoth-Fehring

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Nina Langoth-Fehring is a consultant for the development of medicinal products and medical devices, as well as quality management for pharmaceuticals. She began consulting in March 2020 after holding several executive positions in the pharmaceutical industry. Nina holds a master's in pharmacy and a doctorate in pharmaceutical technology and has been active in pharmaceutical industry for more than 15 years in research & development positions, as a qualified person and as a business manager.

Recent Accomplishments (2020-2022)

- Establishment of pharmaceutical-quality management systems in biotech and start-up companies acting as sponsors for clinical studies (GCP compliance)
- Support of a bioanalytical company to become GCLP compliant
- Update of a sponsor's GCP SOPs in accordance with the Clinical Trial Regulations
- Quality (supplier qualification) audits of GMP manufacturers (incl. ATMPs), contract research organizations, and bioanalytical laboratories
- Support of IMPD creation
- Business Manager for the manufacture and wholesale distribution of medicinal products for the Austrian subsidiary of a European pharmaceutical company
- Gap analysis of a QMS regarding compliance with the Medical Device Regulations

Professional Experience

2020-present Successful self-employed pharma consultant (QP services, QM services, interim management as Business Manager for the manufacture and wholesale of medicinal products, product development strategies)

2019-2020 Business Manager, Head of R&D and GMP/Quality representative at Cannabeo GmbH, Vienna, Austria (Cannabeo produces, develops and registers medicinal cannabis products); Establishment of a QMS at a new site for medical cannabis production.

2016-2019 Corporate Director of Research & Development and Qualified Person at CROMA-PHARMA GmbH, Leobendorf, Austria; Heading the R&D team of approx. 30 employees.

2011-2016 Director of Development Department and Qualified Person at CROMA-PHARMA GmbH, Leobendorf, Austria; Heading the Development team of approx.. 13 employees.

2009-2013 Lectureship at University of Applied Sciences in Tulln, Austria; Title of the lecture Formulation and Stabilization of Drug Products

2009-2011 Qualified Person and Head of Release Department at CROMA-PHARMA GmbH, Leobendorf, Austria; Leading the Release Department with 3 employees, in parallel Project Leader for market authorization of a new drug product via the centralized procedure at the EMA

- 2006-2011 Project Leader in Development Department at CROMA-PHARMA GmbH, Leobendorf, Austria; Development of medical devices, development to launch of two food supplements and one cosmetic product.
- 2006-2007 Lectureship, Institute of Pharmaceutical Technology, University of Vienna; Laboratory tutorial in pharmaceutical technology and galenics.
- 2005–2013 Pharmacist, Sonnenapotheke & Apotheke Freindorf, Linz
- 2004–2005 Manager at ThioMatrix GmbH, Innsbruck; Executive in a start-up company, establishment of a new laboratory.

Education and Qualifications

- 2020 Certified GMP Auditor (Concept Heidelberg, Germany)
- 2019 Certification as business manager for manufacture and wholesale of medicinal products
- 2009 Certification by the Austrian Ministry of Health as a Qualified Person
- 2007 Postgraduate course in micronutrients, Danube University, Krems
- 2004 Qualification as certified dispensing pharmacist
- 2000-2003 PhD in Pharmaceutical Technology, University of Vienna
- 2002 Fundamentals of business course at WIFI, Vienna
- 2000 Master's in pharmacy, University of Vienna

Memberships: Member of the Austrian and European Qualified Person Association

Special Skills:

Languages:

German (native)

English (advanced)

Personal Skills:

Excellent time management

Multitasking skills

Problem solving skills

Accuracy

Teamwork



Nina Langoth-Fehringner, January 31st 2023